JUN 2 7 2005

510(k) SUMMARY

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K050500.

Date Prepared: February 23, 2005

Submitted by:

Kimberley Kline
Senior Regulatory Associate

TheraSense, Inc.
1360 South Loop Road
Alameda, CA 94502

Phone: (510) 749-5478
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Device Name: FreeStyle 600 Blood Glucose Monitoring System

Common Name: Blood Glucose Meter and Reagent Test Strips

Classification: Glucose Test System
Class II per 21 CFR 862.1345

Predicate Devices: FreeStyle Blood Glucose Monitoring System, K992684, K000582, K012014, K031260
Precision PCx 2.2.1 Blood Glucose System, K022941

Description: The FreeStyle Blood Glucose Monitoring System comprises an electrochemical biosensor glucose reagent test strip, a handheld meter, a quality control solution, a complete Owner's Booklet and a Quick Reference Guide. A lancing device, lancets and a logbook for recording test results are also included with the system.

When the user inserts a test strip, the meter turns on. The user acquires a blood sample (with the test strip in the meter) by picking up the meter and touching the edge of the test strip at the blood target area, filling the chamber on the strip by capillary action. The meter sounds a tone (beeps) to let the user know that the sample chamber is full and the reaction has begun. When the test is complete, the meter displays the glucose reading on its liquid crystal display (LCD).

Intended Use:

The FreeStyle 600 Blood Glucose Monitoring System is intended for in vitro diagnostic use for the quantitative measurement of glucose in fresh capillary, venous, arterial and neonatal whole blood samples. The FreeStyle 600 Blood Glucose Monitoring System is for testing outside the body (in vitro diagnostic use). The FreeStyle 600 Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels.

Principle of Operation:

The user obtains a blood sample using a conventional lancing technique on the finger, forearm, upper arm, hand, thigh, calf, or palm. The user inserts a test strip into the meter, which turns the meter on. When the strip is touched to the blood drop, the sample chamber on the strip fills by capillary action in approximately 2 seconds. The blood sample volume required is approximately 0.3 microliters (300 nanoliters), which can be obtained from the finger, forearm, upper arm, hand, thigh, calf, or palm. Test results are displayed in about 15 seconds. The time required to display test results varies depending on the blood glucose concentration (approximately 15 to 45 seconds).

The glucose in the blood sample reacts with the glucose dehydrogenase enzyme to yield gluconolactone, and produces a small electrical current. This current is measured by the FreeStyle meter and displayed as a glucose level.

Comparison to Predicate Device:

The FreeStyle 600 Blood Glucose Monitoring System has the same technological characteristics as the predicate device, FreeStyle™ Blood Glucose Monitoring System, K992684, K000582, K012014, K031260 and the same intended use as the Precision PCx 2.2.1 Blood Glucose System, K022941.

Performance Studies:

The performances of the FreeStyle 600 Blood Glucose Monitoring System was studied in the laboratory and in clinical settings by healthcare professionals. The studies demonstrated that healthcare professionals could obtain blood glucose results that are substantially equivalent to a comparative method.

Conclusion:

Results of laboratory and clinical testing demonstrates that the performance of the FreeStyle 600 Blood Glucose Monitoring System when used according to the intended use stated above is acceptable and comparable to the performance to a comparative method. Clinical test results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 27 2005

Ms. Kimberley Kline
Senior Regulatory Associate
TheraSense, Inc.
1360 South Loop Road
Alameda, CA 94502

Re: k050500
Trade/Device Name: FreeStyle 600 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: May 24, 2005
Received: May 25, 2005

Dear Ms. Kline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050500

Device Name: FreeStyle 600 Blood Glucose Monitoring System

Indications For Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050500